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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,686	12/10/2003	Yaron Ilan	Enz-64(D2)	9035

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ENZO BIOCHEM, INC.
527 MADISON AVENUE (9TH FLOOR)
NEW YORK, NY 10022

EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,686	ILAN ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a process for treating a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite or a reagent, classified in class 424 or 514, subclass-indeterminate because of functionality defined substance.

II. Claims 25-49, drawn to a process for treating a disease in a mammalian subject comprising obtaining cells from said subject, treating said cell with an effective amount of a mammalian intermediary metabolite or a reagent so as to raise the intracellular level of said metabolite in said cells, and transferring said treated cells to said subject; classified in class 435, subclass 325.

III. Claims 50-62, drawn to a process for treating a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian metabolite so as to modulate or change at least one component in the immune system of said subject, classified in class 424 or 514, subclass-indeterminate because of functionality defined substance.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are independent inventions and thus are subject to restriction. The inventions are independent processes in that the methods are not dependent on each other, not disclosed as to be used together and have different functions, modes of operation or effects.

The inventions of Group I is independent from Group II. The invention of Group I does not depend on the invention of Group II, not disclosed as useable together, and have different modes of operation. The invention of Group I require the active method step of administration of either a mammalian intermediary metabolite or a reagent; whereas, the invention of Group II require the active method steps of obtaining cells from said subject, treating said cell with an effective amount of a mammalian intermediary metabolite so as to raise the intracellular level of said metabolite in said cells, and transferring said treated cells to said subject. Therefore, the invention of Group I is independent from the inventions of Group II.

The inventions of Groups I-II are independent from Group III. The inventions of Groups I-II do not depend on the invention of Group III, not disclosed as useable together, and have different functions. The invention of Group III is directed at modulating or changing at least one component in the immune system; whereas, the inventions of Groups I-II is not directed at modulating or changing at least one component in the immune system. Therefore, the invention of Group III is independent from the inventions of Groups I-II.

3. If Applicant elects Group I or II, Applicant must further elect either an intermediary metabolite or a reagent. The Examiner attempted to seek clarification on the similarity between an intermediary metabolite and a reagent by reviewing the specification. However, such clarification is not provided by the disclosure. Thus, the instant requirement is based on the assumption that a reagent is a composition that is structurally different from that of an intermediary metabolite, thereby rendering an intermediary metabolite patentably distinct from that of a reagent.

If Applicant elects Group I, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method: raising the intracellular, extracellular, or serum level of the metabolite. Each of these listed biological activities is patentably distinct from one another. An increase in the serum level of the metabolite is different from an increase in the intracellular and extracellular level of the metabolite.

If Applicant elects Group II, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis.

Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method: raising the intracellular, extracellular, or serum level of the metabolite; increases the rate of production of said mammalian intermediary metabolite; or decreases the rate of degradation or turnover of said mammalian intermediary metabolite. Each of these listed biological activities is patentably distinct from one another. An increase in the serum level of the metabolite is different from an increase in the intracellular and extracellular level of the metabolite or decreases the rate of degradation or turnover of said mammalian intermediary metabolite.

If Applicant elects Group III, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a

serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the type of cells to be obtained: peripheral blood monocytes (PBMCs), dendritic cells, T cells, stem cells, NK cells, NKT cells, or CD1d cells. Each of the listed type of cells is patentably distinct from one another. T cells differ from those of NK cells and stem cells. Each has a different from in the immune system of a mammalian host.

If Applicant elects Group IV, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method: increasing the intracellular level of the metabolite; increases the rate of production of said mammalian intermediary metabolite; or decreases the rate of degradation or turnover of said mammalian intermediary metabolite. Each of these listed biological activities is patentably distinct from one another. An increase in the serum level of the metabolite is different from an increase in the intracellular and extracellular level of the metabolite or decreases the rate of degradation or turnover of said mammalian intermediary metabolite.

d) the type of cells to be obtained: peripheral blood monocytes (PBMCs), dendritic cells, T cells, stem cells, NK cells, NKT cells, or CD1d cells. Each of the listed type of cells is patentably distinct from one another. T cells differ from those of NK cells and stem cells. Each has a different role from in the immune system of a mammalian host.

If Applicant elects Group V, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a

significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method: modulate or change cellular, humoral, or cytokine elements of the immune system. Each of these listed biological activities is patentably distinct from one another. A modulation or change in the cellular response is different from that of a humoral and cytokine related immune response.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper. The search required for any of Groups I-V is not required for the other, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

JAMES HOUSEL 10/1/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600